

## REMARKS

### STATUS OF THE CLAIMS

Claims 1-28 were pending. Claims 29-35 were previously cancelled. New claims 36-38 have been added. After entry of the amendments, claims 1-28 and 36-37 will be pending.

### ARGUMENTS IN TRAVERSE OF RESTRICTION REQUIREMENT

The Examiner first issued a restriction requirement in this case on January 31, 2006, dividing the method claims from kit claims. Applicant responded by cancelling the kit claims, and pursuing them in a divisional. Also in the Office Action of January 31, 2006, the Applicant was required to elect a species of one of the Tables recited in the claimed invention. Following this restriction requirement, an Office Action on the merits was issued on June 23, 2006, and a Final Office Action was issued on March 23, 2007, both of which were responded to by the Applicant. In the most recent and fourth Office Action of August 30, 2007, the Examiner not only withdrew the prior species election requirement, but issued a new restriction that requires the Applicant to elect a particular Table as an actual restriction rather than a species election. The Examiner also issued a further restriction in which the Applicant not only must elect a Table, but further must elect a particular percentage combination of sequences from within that Table. Still further, the Applicant must also select out of the sequences in the Table the specific sequences that make up the combination. The Examiner indicated that this is a restriction and not a species election.

In the current Office Action of August 30, 2007, the Examiner cited to MPEP 803.04 when issuing the restriction requiring selection of one combination of sequences for examination, and the Examiner further pointed via a brief phone call with Applicant's representative, Antonia Sequeira, on July 17, 2007 to the Official Gazette Notice of March 27, 2007 that rescinded the partial waiver of 37 CFR 1.141 for restriction practice involving nucleotide sequences. However, this Official Gazette Notice specifically states that while the Notice is applicable to pending applications, "supplemental restriction requirements will **not** be advanced in applications that have **already received an action on their merits** in the absence of extenuating circumstances," (emphasis added). The Examiner has identified no extenuating circumstances,

and the Applicants have already received and responded to several Office Actions in this case. Thus, a supplemental restriction requirement is improper in this case, as specifically stated in the Official Gazette Notice. Even if there were extenuating circumstances sufficient to allow the Examiner rescind his previously issued species election and replace it with a restriction requirement requiring election of one of the listed Tables, there could not possibly be extenuating circumstances so dire as to require the more drastic restriction of electing not only a specific percentage combination of genes in the Table, but also electing the specific genes that make up that combination. This is a much more narrow restriction that would make it nearly impossible for Applicants to effectively claim their invention as originally claimed.

The stated goal in the Official Gazette Notice of March 27, 2007 is to “enhance the Office’s ability to provide a focused, thorough and quality examination of polynucleotide inventions, and to lead to consistency in the examination of the polynucleotide molecules regardless of the manner in which they are claimed.” Here, the late issuance of multiple completely new and substantially more limiting restrictions directly contravenes the stated goal of the Notice by requiring the Applicant to re-start prosecution yet again. This action shifts the burden of prosecution from the Examiner to the Applicant, requiring the Applicant to pursue an impracticable number of divisional applications at an exorbitant cost in order to protect his invention as originally claimed.

The Examiner also indicated that Applicant should identify any sequences in the elected combination that are believed to be novel to aid in the searching of the combination. As stated in prior Office Action responses, however, the invention is the combination of prior art sequences for classifying biological samples on the basis of gene expression patterns derived from those samples. Thus, none of the sequences themselves are believed to be novel sequences, but instead the combination of sequences in the kit as recited in the claimed invention is believed to be novel.

In addition, the section MPEP 803.04 that the Examiner cites to for support for his restriction was superseded by the Official Gazette Notice, as indicated by the Notice. Further, the MPEP section provides examples relied on by the Examiner that are each different from the

claimed invention. The Example C provided in the MPEP that the Examiner relied upon refers to requiring an Applicant to elect one combination for which the Examiner searches each sequence in the combination in a sequence-by-sequence manner until a novel combination is found, and such a novel combination renders the whole combination allowable. Here, however, Applicant has already identified that the sequences themselves are not believed to be novel, but it is instead the combination of sequences that constitutes the claimed invention. Thus, the Examiner need not search each sequence in the elected Table, but instead should be searching the prior art for disclosure of a kit including *all* of the sequences in the combination. For example, to search for Signature 1 of Table 69a, the Examiner should be conducting only a single search for a prior art reference that includes all 5 of the recited genes in the signature, as opposed to searching through the prior art gene-by-gene. This search burden is much smaller. Further, Example C in MPEP 803.04 recites a combination of at least thirty DNA fragments selected from a group of 1,000 for which restriction was proper, but here, Table 69 includes only 14 sequences, as opposed to various combinations of 1,000.

As stated above, in the Office Action of January 31, 2006, the Examiner introduced a restriction requirement in which the Applicant was required to elect a species of one of the Tables recited in the claimed invention, and Applicant appropriately responded. The Examiner later followed with an Office Action on June 23, 2006 rejecting claims 24-28 under 35 U.S.C. 112, first paragraph and requiring that the Applicant provide a sequence listing for the invention claimed to accommodate the Examiner's ability to conduct a prior art search. Because Applicant had already received what Applicant expected to be the final restriction requirement, Applicant assumed that this species election would stand. Thus, Applicant relied on this species election in deciding to provide a sequence listing for every single sequence in every Table claimed at great effort and expense to accommodate the Examiner's search. Had the Applicant known that he would later be limited in another restriction requirement to just a few sequences, Applicant would have saved a great deal of expense and effort by providing a sequence listing for only those few sequences.

For at least the reasons stated above, Applicant believes that this current restriction requirement received in the Office Action of August 30, 2007 is improper and should be withdrawn given the lateness in prosecution, the statement in the Official Gazette Notice that such supplemental restrictions “will not be advanced,” and also given the hardship placed upon the Applicant by this further restriction.

While the Applicant believes that the entire restriction requirement is improper, if the Examiner disagrees, Applicant respectfully requests that the Examiner require only a species election between the combinations recited in the elected Table. If the Examiner agrees, Applicant elects the species including 60% of the sequences of Table 69, where the elected species includes the following sequences: **MGC5466** (SEQ. ID. 2240), **Wnt5A** (SEQ. ID. 2241), **KIAA0476** (SEQ. ID. 2243), **ITPR1** (SEQ. ID. 2245), **TCF2** (SEQ. ID. 2247), **CHAF1A** (SEQ. ID. 2250), **CDS2** (SEQ. ID. 2252), and **IER3** (SEQ. ID. 2254).

If this is still unacceptable, the Applicant requests that Examiner at least allow the Applicant to claim three signatures. Specifically, Table 69 of the specification recites three signatures of interest to the Applicant for claiming in the present Application. In the interest of making this clearer, Applicant has amended the specification to recite Tables 69a, b, and c. New claims 36-38 have been added for clarity to recite these three signatures. Election of the signatures of claims 36-38 would only require three searches, since again the Examiner should be searching for each combination, not gene-by-gene. Thus, Applicant elects the inventions of claims 36-38 reciting the three signatures, and claims 24-28 can then be cancelled. The remaining claims encompass the elected invention

In the event that the Examiner still disagrees, the Applicant requests that the Examiner contact the Applicant’s representative to discuss an alternative arrangement that is acceptable to the Examiner, yet imposes less hardship on the Applicant than the currently stated restriction requirement of August 30, 2007. If this is not possible and none of the stated alternatives are acceptable, Applicant notes finally that an election is set forth above below to ensure that this reply is responsive to the restriction requirement.

## ELECTION

As stated above, Table 69 of the specification recites three signatures of interest to the Applicant for claiming in the present Application. Applicant would like to elect signature 1 of Table 69 for the current application. The Examiner has required the Applicant to elect a particular Table. The Examiner has also required the Applicant to elect whether the combination includes 60%, 70%, 80%, 90%, or all of the genes of the Table, and to identify the particular genes if the combination is less than all of the genes. Here, the Applicant would like to elect all of the genes in Table 69a which includes Signature 1 having the following genes: **MGC5466** (SEQ. ID. 2240), **Wnt5A** (SEQ. ID. 2241), **KIAA0476** (SEQ. ID. 2243), **ITPR1** (SEQ. ID. 2245), and **TCF2** (SEQ. ID. 2247). For clarity, Applicant has specifically recited this signature in new claim 36. Thus, Applicant elects the combination recited in claim 36. If the Examiner accepts this, Applicant also requests cancellation of claims 24-28. The remaining claims other than 37 and 38 encompass the elected invention. This election is made with traverse.

If for some reason the Examiner does not accept the election stated above, to ensure responsiveness, Applicant elects Table 69, and further elects the combination of 60% of the genes of Table 69, in which the combination includes the following nucleotide sequences: **MGC5466** (SEQ. ID. 2240), **Wnt5A** (SEQ. ID. 2241), **KIAA0476** (SEQ. ID. 2243), **ITPR1** (SEQ. ID. 2245), and **TCF2** (SEQ. ID. 2247), **CHAF1A** (SEQ. ID. 2250), **CDS2** (SEQ. ID. 2252), and **IER3** (SEQ. ID. 2254). Each of claims 1-24 encompass this invention. This election is made with traverse.

If the Examiner has any questions concerning this Response, the Examiner is invited to telephone Applicant's representative at (650) 335-7185.

Respectfully submitted,  
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